

HOUSE No. 2691

By Mr. Koutoujian of Waltham, petition of Peter J. Koutoujian and others for legislation to prevent the distribution of counterfeit drugs. Public Health.

The Commonwealth of Massachusetts

PETITION OF:

Peter J. Koutoujian
John W. Scibak

Anne M. Gobi
Joyce A. Spiliotis

In the Year Two Thousand and Five.

AN ACT TO PREVENT THE DISTRIBUTION OF COUNTERFEIT DRUGS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Definitions.

2 (a) Authentication — Authentication means to affirmatively
3 verify before any distribution of a prescription drug occurs that
4 each transaction listed on the Pedigree Paper has occurred.

5 (b) Facility — “Facility” means a facility of a wholesale dis-
6 tributor where prescription drugs are stored, handled, repackaged,
7 or offered for sale.

8 (c) Immediate Family — The term “immediate family”
9 includes a person’s spouse, children, parents, siblings, the spouses
10 of a person’s children, and the spouses of a person’s siblings.

11 (d) Pedigree Paper — A “Pedigree Paper” is a document or
12 electronic file containing information that records each distribu-
13 tion of any given prescription drug, from sale by a pharmaceutical
14 manufacturer, through acquisition and sale by any wholesale dis-
15 tributor or repackager, until final sale to a pharmacy or other
16 person dispensing or administering the prescription drug.

17 (e) Prescription Drug — “Prescription drug” means any drug
18 (including any biological product, except for blood and blood
19 components intended for transfusion or biological products that
20 are also medical devices) required by Federal law (including Fed-

21 eral regulation) to be dispensed only by a prescription, including
22 finished dosage forms and bulk drug substances subject to section
23 503(b) of the Federal Food, Drug and Cosmetic Act (“FFDCA”).

24 (f) Repackage — “Repackage” includes repackaging or other-
25 wise changing the container, wrapper, or labeling to further the
26 distribution of a prescription drug.

27 (g) Repackager — “Repacker” means a person who repackages.

28 (h) Wholesale Distributor — “Wholesale distributor” means
29 anyone engaged in the wholesale distribution of prescription
30 drugs, including, but not limited to, manufacturers (unless speci-
31 fied otherwise); repackagers; own-label distributors; private-label
32 distributors; jobbers; brokers; warehouses, including manufac-
33 turers’ and distributors’ warehouses, chain drug warehouses, and
34 wholesale drug warehouses; independent wholesale drug traders;
35 and retail pharmacies that conduct wholesale distribution.

1 SECTION 2. Wholesale Drug Distributor Licensing Require-
2 ment/Minimum Requirements for Licensure.

3 (a) Every wholesale distributor who engages in the wholesale
4 distribution of prescription drugs must be licensed by the State
5 licensing authority in the State in which it resides, and every non-
6 resident wholesale distributor must be licensed in a State if it
7 ships prescription drugs into that State, in accordance with this
8 Act before engaging in wholesale distributions of wholesale pre-
9 scription drugs.

10 (b) The State licensing authority shall require the following
11 minimum information from each wholesale distributor applying to
12 get a license under paragraph (a) and as part of any renewal of
13 such license:

14 (1) The name, full business address, and telephone number of
15 the licensee.

16 (2) All trade or business names used by the licensee.

17 (3) Addresses, telephone numbers, and the names of contact
18 persons for all facilities used by the licensee for the storage, han-
19 dling, and distribution of prescription drugs.

20 (4) The type of ownership or operation (i.e., partnership, corpo-
21 ration, or sole proprietorship).

22 (5) The name(s) of the owner and/or operator of the licensee,
23 including:

- 24 (A) If a person, the name of the person;
- 25 (B) If a partnership, the name of each partner, and the name of
26 the partnership;
- 27 (C) If a corporation, the name and title of each corporate officer
28 and director, the corporate names, and the name of the State of
29 incorporation; and
- 30 (D) If a sole proprietorship, the full name of the sole proprietor
31 and the name of the business entity.
- 32 (6) A list of all licenses and permits issued to the applicant by
33 any other State that authorizes the applicant to purchase or pos-
34 sess prescription drugs.
- 35 (7) The name of the manager of the facility that is applying for
36 the initial license, or to renew the license, the next four highest
37 ranking employees responsible for prescription drug wholesale
38 operations for the facility, and the name of all affiliated parties for
39 the facility, together with the personal information statement and
40 fingerprints required pursuant to subparagraph (9) for each of
41 such persons.
- 42 (8) Designated Representative — The name of the applicant's
43 designated representative for the facility, together with the per-
44 sonal information statement and fingerprints, required pursuant to
45 subparagraph (9) for such person.
- 46 (9) Personal Information Statement — Each person required by
47 subparagraphs (7) and (8) to provide a personal information state-
48 ment and fingerprints shall provide the following information to
49 the State:
- 50 (A) The person's places of residence for the past 7 years;
- 51 (B) The person's date and place of birth;
- 52 (C) The person's occupations, positions of employment, and
53 offices held during the past 7 years;
- 54 (D) The principal business and address of any business, corpo-
55 ration, or other organization in which each such office of the
56 person was held or in which each such occupation or position of
57 employment was carried on;
- 58 (E) Whether the person has been, during the past 7 years, the
59 subject of any proceeding for the revocation of any license and, if
60 so, the nature of the proceeding and the disposition of the pro-
61 ceeding;

62 (F) Whether, during the past 7 years, the person has been
63 enjoined, either temporarily or permanently, by a court of compe-
64 tent jurisdiction from violating any Federal or State law regulating
65 the possession, control, or distribution of prescription drugs,
66 together with details concerning any such event;

67 (G) A description of any involvement by the person with any
68 business, including any investments, other than the ownership of
69 stock in a publicly traded company or mutual fund, during the past
70 7 years, which manufactured, administered, prescribed, distrib-
71 uted, or stored pharmaceutical products and any lawsuits in which
72 such businesses were named as a party;

73 (H) A description of any felony criminal offense of which the
74 person, as an adult, was found guilty, regardless of whether adju-
75 dication of guilt was withheld or whether the person pled guilty or
76 nolo contendere. If the person indicates that a criminal conviction
77 is under appeal and submits a copy of the notice of appeal of that
78 criminal offense, the applicant must, within 15 days after the dis-
79 position of the appeal, submit to the State a copy of the final
80 written order of disposition;

81 (I) A photograph of the person taken in the previous 30 days;

82 (J) A set of fingerprints for the person on a form and under pro-
83 cedures specified by the State, together with payment of an
84 amount equal to the costs incurred by the State for the criminal
85 record check of the person. Once the person has submitted a set
86 of fingerprints for the initial license, the person need not submit a
87 second set of fingerprints for the renewal; and

88 (c) The information required pursuant to paragraph (b) shall be
89 provided under oath.

90 (d) The State shall not issue or renew a wholesale distributor
91 license of an applicant, unless the State determines that the desig-
92 nated representative meets the following qualifications:

93 (1) Is at least 21 years of age;

94 (2) Has been employed full time for at least 3 years in a phar-
95 macy or with a wholesale distributor in a capacity related to the
96 dispensing and distribution of, and recordkeeping relating to, pre-
97 scription drugs;

98 (3) Has received a score of 75 percent or more on an examina-
99 tion given by the State licensing authority regarding Federal and
100 State laws governing wholesale distribution of prescription drugs.

101 A designated representative, who has previously served in that
102 capacity, must re-take the State examination each time an appli-
103 cant lists the person as the designated representative in an applica-
104 tion for license renewal;

105 (4) Is employed by the applicant full time in a managerial level
106 position;

107 (5) Is actively involved in and aware of the actual daily opera-
108 tion of the wholesale distributor;

109 (6) Is physically present at the facility of the applicant during
110 regular business hours, except when the absence of the designated
111 representative is authorized, including but not limited to, sick
112 leave and vacation leave;

113 (7) Is serving in the capacity of a designated representative for
114 only one applicant at a time;

115 (8) Does not have any convictions under any Federal, State, or
116 local laws relating to wholesale or retail prescription drug distrib-
117 ution or distribution of controlled substances; and

118 (9) Does not have any felony convictions under Federal, State,
119 or local laws.

120 (e) The State shall submit the fingerprints provided by a person
121 with an initial or a renewal license application for a statewide
122 criminal record check and for forwarding to the Federal Bureau of
123 Investigation for a national criminal record check of the person.

124 (f) Bond Requirement — The State licensing authority shall
125 require every wholesale distributor applying for a new license or
126 the renewal of a license to submit a bond of at least, or other
127 equivalent means of security acceptable to the State, such as an
128 irrevocable letter of credit or a deposit in a trust account or finan-
129 cial institution, payable to a fund established by the State pursuant
130 to paragraph (g). The purpose of the bond is to secure payment of
131 any fines or penalties imposed by the State and any fees and costs
132 incurred by the State regarding that license, which are authorized
133 under State law and which the licensee fails to pay 30 days after
134 the fines, penalties, or costs become final. The State may make a
135 claim against such bond or security until 1 year after the licensee's
136 license ceases to be valid.

137 (g) The State licensing authority shall establish a fund, separate
138 from its other accounts, in which to deposit the wholesale distrib-
139 utor bonds.

140 (h) If a wholesale distributor distributes prescription drugs from
141 more than one facility, the wholesale distributor shall obtain a
142 license for each facility.

143 (i) Changes in any information in paragraph (b) of this section
144 shall be submitted to the State licensing authority as required by
145 such authority.

1 SECTION 3. Minimum Restrictions on Transactions.

2 (a) 5 Percent Rule — In any calendar month, a wholesale dis-
3 tributor shall sell, distribute, transfer, or otherwise provide at least
4 95 percent of its total amount of prescription drugs to a pharmacy
5 or other person dispensing or administering the drug.

6 (b) Purchases and Receipts from Pharmacies:—

7 (1) A wholesale distributor shall not purchase or otherwise
8 receive a prescription drug from a pharmacy, except that a whole-
9 sale distributor may receive a prescription drug from a pharmacy
10 if the prescription drug was originally purchased by the pharmacy
11 from the wholesale distributor.

12 (2) A wholesale distributor who meets the exception in sub-
13 paragraph (1), shall not:

14 (A) Receive from a pharmacy an amount or quantity of a pre-
15 scription drug larger than the amount or quantity that was origi-
16 nally sold by the wholesale distributor to the pharmacy; or

17 (B) Pay the pharmacy an amount, either in cash or credit, more
18 than the pharmacy originally paid the wholesale distributor for the
19 prescription drug.

20 (c) Sale, Distribution, or Transfer to an Unlicensed Person —
21 A manufacturer or wholesale distributor shall furnish prescription
22 drugs only to a person licensed by the appropriate State licensing
23 authorities. Before furnishing prescription drugs to a person not
24 known to the manufacturer or wholesale distributor, the manufac-
25 turer or wholesale distributor shall affirmatively verify that the
26 person is legally authorized to receive the prescription drugs by
27 contacting the appropriate State licensing authorities.

28 (d) Prescription drugs furnished by a manufacturer or wholesale
29 distributor shall be delivered only to the premises listed on the
30 license; provided that the manufacturer or wholesale distributor
31 may furnish prescription drugs to an authorized person or agent of

32 that person at the premises of the manufacturer or wholesale dis-
33 tributor if:

34 (1) The identity and authorization of the recipient is properly
35 established; and

36 (2) This method of receipt is employed only to meet the imme-
37 diate needs of a particular patient of the authorized person.

38 Prescription drugs may be furnished to a hospital pharmacy
39 receiving area provided that a pharmacist or authorized receiving
40 personnel signs, at the time of delivery, a receipt showing the type
41 and quantity of the prescription drug so received. Any discrep-
42 ancy between receipt and the type and quantity of the prescription
43 drug actually received shall be reported to the delivering manufac-
44 turer or wholesale distributor by the next business day after the
45 delivery to the pharmacy receiving area.

46 (e) A manufacturer or wholesale distributor shall not accept
47 payment for, or allow the use of, a person or entity's credit to
48 establish an account for the purchase of prescription drugs from
49 any person other than the owner(s) of record, the chief executive
50 officer, or the chief financial officer listed on the license of a
51 person or entity legally authorized to receive prescription drugs.
52 Any account established for the purchase of prescription drugs
53 must bear the name of the licensee.

1 SECTION 4. Pedigree.

2 (a) In General — Each person who is engaged in the wholesale
3 distribution of a prescription drug (including repackagers, but
4 excluding the original manufacturer of the finished form of the
5 prescription drug), shall provide a Pedigree Paper or electronic
6 file identifying each sale, trade or transfer of a prescription drug
7 when a prescription drug is sold, traded or transferred to any other
8 person. If a pharmacy sells a drug to any person that is not the
9 final consumer, the pharmacy shall provide to the person
10 acquiring the prescription drug a Pedigree Paper identifying each
11 sale, trade or transfer of a prescription drug. Sale, trade or
12 transfer of a prescription drug between licensees with a common
13 ownership are not subject to this section.

14 (b) Authentication — Each person who is engaged in the
15 wholesale distribution of a prescription drug (including repack-
16 agers, but excluding the original manufacturer of the finished

17 form of the prescription drug), who is in possession of a Pedigree
18 Paper for a prescription drug and attempts to further distribute that
19 prescription drug, shall affirmatively verify before any distribu-
20 tion of a prescription drug occurs that each transaction listed on
21 the Pedigree Paper has occurred.

22 (c) Contents — The Pedigree Paper shall:

23 (1) Include all necessary identifying information concerning
24 each sale in the chain of distribution of the product from the man-
25 ufacturer, through acquisition and sale by any wholesale distrib-
26 utor or repackager, until final sale to a pharmacy or other person
27 dispensing or administering the drug. At minimum, the necessary
28 chain of distribution information shall include:

29 (A) Name, address, telephone number, and if available, the e-
30 mail address, of each owner of the prescription drug, and each
31 wholesale distributor who does not take title to the prescription
32 drug;

33 (B) Signature of each owner of the prescription drug and each
34 wholesale distributor who does not take title to the prescription
35 drug;

36 (C) Name and address of each location from which the product
37 was shipped, if different from the owner's;

38 (D) Transaction dates; and

39 (E) Certification that each recipient has authenticated the Pedi-
40 gree Paper. [NABP requires that the *designated representative of*
41 *the wholesale distributor* certify that all information in the pedi-
42 gree is true and accurate under penalty of perjury].

43 (2) At minimum, the Paper Pedigree shall also include the:

44 (A) Name of the prescription drug;

45 (B) Dosage form and strength of the prescription drug;

46 (C) Size of the container;

47 (D) Number of containers;

48 (E) Lot number of the prescription drug; and

49 (F) Name of the manufacturer of the finished dosage form.

50 (d) Maintenance Provisions — Each statement shall be:

51 (1) Maintained by the purchaser and the wholesale distributor
52 for 3 years; and

53 (2) Available for inspection or removal upon a request of an
54 authorized officer of the law.

55 (e) Implementation — The state licensing authority adminis-
56 tering this Act shall adopt rules and a form relating to the require-
57 ments of this paragraph no later than [90] days after the effective
58 date of this Act.

1 SECTION 5. Enforcement — Order to Cease Distribution of a
2 Drug.

3 (a) Order to Cease Distribution of a Prescription Drug — If the
4 State finds that there is a reasonable probability that:

5 (1) A wholesale distributor has:

6 (A) [Knowingly] violated a provision in this Act, or

7 (B) Falsified a Paper Pedigree, or [knowingly] sold, distributed,
8 transferred, manufactured, repackaged, handled, or held a counter-
9 feit prescription drug intended for human use,

10 (2) The prescription drug at issue in paragraph (1) could cause
11 serious, adverse health consequences or death, and

12 (3) Other procedures would result in unreasonable delay, the
13 State shall issue an order requiring the appropriate person
14 (including the manufacturers, distributors, or retailers of the drug)
15 to immediately cease distribution of the drug.

16 (b) An order under paragraph (a) shall provide the person sub-
17 ject to the order with an opportunity for an informal hearing, to be
18 held not later than 10 days after the date of the issuance of the
19 order, on the actions required by the order. If, after providing an
20 opportunity for such a hearing, the State determines that inade-
21 quate grounds exist to support the actions required by the order,
22 the State shall vacate the order.

1 SECTION 6. Prohibited Acts.

2 It is unlawful for a person to perform or cause the performance
3 of or aid and abet any of the following acts in this State:

4 (a) Failure to obtain a license in accordance with this Act, or
5 operating without a valid license when a license is required by this
6 Act;

7 (b) Selling, distributing, transferring, or otherwise providing
8 prescription drugs in violation of the 5 Percent Rule established in
9 Section 3(a) of this Act;

10 (c) Purchasing or otherwise receiving a prescription drug from
11 a pharmacy, unless the requirements in Section 3(b) of this Act are
12 met;

13 (d) The sale, distribution, or transfer of a prescription drug to a
14 person that is not authorized under the law of the jurisdiction in
15 which the person receives the prescription drug to receive the pre-
16 scription drug, in violation of Section 3(c) of this Act;

17 (e) Failure to deliver prescription drugs to specified premises,
18 as required by Section 3(d) of this Act;

19 (f) Accepting payment or credit for the sale of prescription
20 drugs in violation of Section 3(e) of this Act;

21 (g) Failure to maintain or provide Pedigree Papers as required
22 by this Act;

23 (h) Failure to obtain, pass, or authenticate a Paper Pedigree, as
24 required by this Act;

25 (i) Providing the State or any of its representatives or any fed-
26 eral official with false or fraudulent records or making false or
27 fraudulent statements regarding any matter within the provisions
28 of this Act;

29 (j) Obtaining or attempting to obtain a prescription drug by
30 fraud, deceit, misrepresentation or engaging in misrepresentation
31 or fraud in the distribution of a prescription drug;

32 (k) The manufacture, repacking, sale, transfer, delivery, hold-
33 ing, or offering for sale any prescription drug that is adulterated,
34 misbranded, counterfeit, suspected of being counterfeit, or has
35 otherwise been rendered unfit for distribution;

36 (l) The adulteration, misbranding, or counterfeiting of any pre-
37 scription drug;

38 (m) The receipt of any prescription drug that is adulterated,
39 misbranded, stolen, obtained by fraud or deceit, counterfeit, or
40 suspected of being counterfeit, and the delivery or proffered
41 delivery of such drug for pay or otherwise; and

42 (n) The alteration, mutilation, destruction, obliteration, or
43 removal of the whole or any part of the labeling of a prescription
44 drug or the commission of any other act with respect to a prescrip-
45 tion drug that results in the prescription drug being misbranded.

1 SECTION 7. Penalties.

2 (a) Violations — If a person engages in the wholesale distribu-
3 tion of prescription drugs in violation of this Act, the person shall
4 be imprisoned for not more than 15 years, and fined not more than
5 \$50,000, or both.

6 (b) Knowing Violations — If a person knowingly engages in
7 wholesale distribution of prescription drugs in violation of this
8 Act, the person shall be imprisoned for any term of years, or fined
9 not more than \$500,000, or both.